DEC 1 2 2001

**Sterling Medivations, Inc.**
**25285 La Loma Drive**
**Los Altos Hills, CA 94022**
**650-949-0470 (voice)**
**650-949-0342 (fax)**

510(k) SUMMARY

**Date Submitted:** November 9. 2001

**Submitter:** Sterling Medivations, Inc. 25285 La Loma Drive, Los Altos Hills, CA 94022
Company Phone 650-949-0470, Company fax 650-949-0342

**Contact:** Joel Douglas, Chief Technology Officer
Sterling Medivations, Inc.
Applicant Phone 650-814-4083, Applicant Fax 650-949-0342

**Trade Name of Device:** Simplicity™ Infusion reservoir for use to infuse medicine, including insulin, from an external infusion pump.

**Common Name of Device:** Infusion pump

**Classification Name:** Infusion pump; Class: II Panel: 80
Procodes: list all the following that apply
FRN – Pump infusion.

**Predicate Device:** The predicate device for Sterling's Simplicity™ Infusion reservoir is the MiniMed 3.0 ml reservoir FDA 510 (k) K991936.

**Description of the New Device:** for the Simplicity™ Infusion reservoir for use with MiniMed pumps. The Simplicity Infusion reservoir is a single use 3.0 ml piston syringe consisting of a hollow barrel, movable plunger with O-rings for sealing, and a male Luer lock fitting at the distal end of the barrel. The device is used in conjunction with an external infusion pump and infusion set to deliver medication subcutaneous. The male luer fitting of the reservoir is connected to the female Luer fitting of an infusion set, and the reservoir is placed in an external infusion pump. The Simplicity infusion reservoir is designed for use with the MiniMed infusion pumps. It is first filled from a standard medication vial by attaching the accompanying disposable luer lock needle and the needle inserted into the septum of the vial. The reservoir is filled similarly to filling an insulin syringe. Once filled and inspected for entrapped air the reservoir is inserted into the MiniMed pump per the pump manufactures instructions and the attaches an infusion set to the reservoir using a standard luer connector to attached it to the infusion set. It is substantially equivalent to the MiniMed 3.0ml reservoir FDA 510(k) K991936.

**Intended Use of the New Device**: The intended use of the Simplicity Infusion reservoir is to provide a means to infuse medicine, including insulin, from an external infusion pump. The reservoir is not intended for use with blood or blood products

**Comparisons of the Technological Features of the New Device and Predicate Device:**

The Simplicity Infusion reservoir proposed for commercial distribution is similar in all significant respects to the existing MiniMed 3.0 ml reservoir FDA 510 (k) K991936.

The materials and manufacturing processes are substantially equivalent, the labeling is substantially equivalent and it has the same intended use as the MiniMed 3.0 ml reservoir FDA 510 (k) K991936.

**Performance Data Supporting Substantial Equivalence**: To provide substantial equivalence the Simplicity Soft QD Euro Infusion Set meets the catheter requirements of:

CDRH 21 C.F.R. section 801.403 INSULIN SYRINGES,

ISO 9626 Stainless steel needle tubing for the manufacture of medical devices,
ISO 11135: 1994 Medical devices – Validation and routine control of ethylene oxide sterilization,
ISO 11138-2:1994 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization.
ISO 594-1: 1986 Conical fittings with a 6% )Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements,
ISO 594-2: 1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings.
ISO 11607: 1997 Packaging for terminally sterilized medical devices,
ISO 8537: 1991 Sterile single use syringes, with or without needle for insulin,
ISO 11135: 1994 Medical devices – Validation and routine control of ethylene oxide sterilization,
ISO 11138-2: 1994 Sterilization of health care products – Biological indicators – Part 2:Biological indicators for ethylene oxide sterilization.

FDA Guidelines on validation of the Limulus Amebocyte Lysate (LAL) Test as an end-product endotoxin test for human and animal parenteral drugs, biological products, and medical devices. ODE Blue Book Memorandum #K90-1.

The design process adhered to is the Center of Devices and Radiological Health. DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS. This Guidance relates to FDA 21 CGR 820.30 and Sub-clause 4.4 of ISO 9001. This is substantially equivalent to the predicate device.

Signed

Joel S. Douglas
Chief Technology Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2001

Mr. Joel Douglas
Chief Technology Officer
Sterling Medivations, Incorporated
25285 La Loma Drive
Los Altos Hills, California 94022-4583

Re: K013767
Trade/Device Name: Simplicity Infusion Reservoir
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: November 9, 2001
Received: November 13, 2001

Dear Mr. Douglas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Simplicity Infusion reservoir

Indications For Use:

The intended use of the Simplicity Infusion reservoir is to provide a means to infuse medicine, including insulin, from an external infusion pump. The reservoir is not intended for use with blood or blood products.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(PER 21 CFR 801.109)

(Optional Format 1-2-96)

Tatiana Cicenia

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013767